Risk Assessment: Evidence Base

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Risk Assessment Components

- Risk assessment Tools
  - Probabilistic Risk Assessment
  - Integrated Medical Model
- Data
  - Astronaut (LSAH)
  - Analogs
- Data informs the decision process for determining flight-qualified crew

What is Risk?

- Definition
  - "The *likelihood* and *severity* of harm or adverse consequence." [*Overview of PRA, 5th NASA PRA Workshop*]
  - "The combination of 1) the *probability* (qualitative or quantitative) that a program or project will experience an undesired event such as a cost overrun, schedule slippage, safety mishap, or failure to achieve a needed technological breakthrough; and 2) the *consequences*, *impact, or severity* of the undesired event were it to occur." [*NPR 8000.4*]
- For human space flight, the set of risks has been identified and catalogued in the *Bioastronautics Roadmap* [*http://bioastroroadmap.nasa.gov/*]

What is PRA?

"PRA is a systematic and comprehensive methodology to evaluate risks associated with every life-cycle aspect of a complex engineered technological entity (e.g., facility, spacecraft, or power plant) from concept definition, through design, construction and operation, and up to removal from service."

Dr. Michael G. Stamatelatos, Director
Safety and Assurance Requirements Division
NASA HQ

As modified for space life sciences:
"PRA is a systematic and comprehensive methodology to evaluate risks associated with every aspect of human health in space flight."

A way to improve decision-making by providing relative order of magnitude differences between risks

- What can go wrong?
- How likely is it?
- What are the consequences?

ISS PRA

- First in NASA to include human health risks
- Risks evaluated based on expert opinion & statistical data, circa 1997
  - Initiating events originated on ground-based historical data
  - Some mitigation events founded only on expert opinion
- Update in progress
  - Astronaut data (e.g., Longitudinal Study of Astronaut Health, LSAH)
  - Actual occurrence of events since 1997
  - Match to current human health standards

ISS PRA Medical Event Models

- ISS Safety & Mission Assurance maintains PRA model of ISS, including crew medical emergencies
- Model compares relative risk of undesired events
  - Loss of Vehicle (LOV)
  - Loss of Crew (LOC)
  - Crew Evacuation (EVAC)
  - Loss of Critical System (LOSys)
- Three types of medical emergency event sequences developed
  1. Treatment is available on board ISS
  2. Treatment is not available on board ISS
  3. Death immediately occurs ("Occupational hazards")
- **Medical issues are leading risk drivers in ISS model for LOC and EVAC end states**

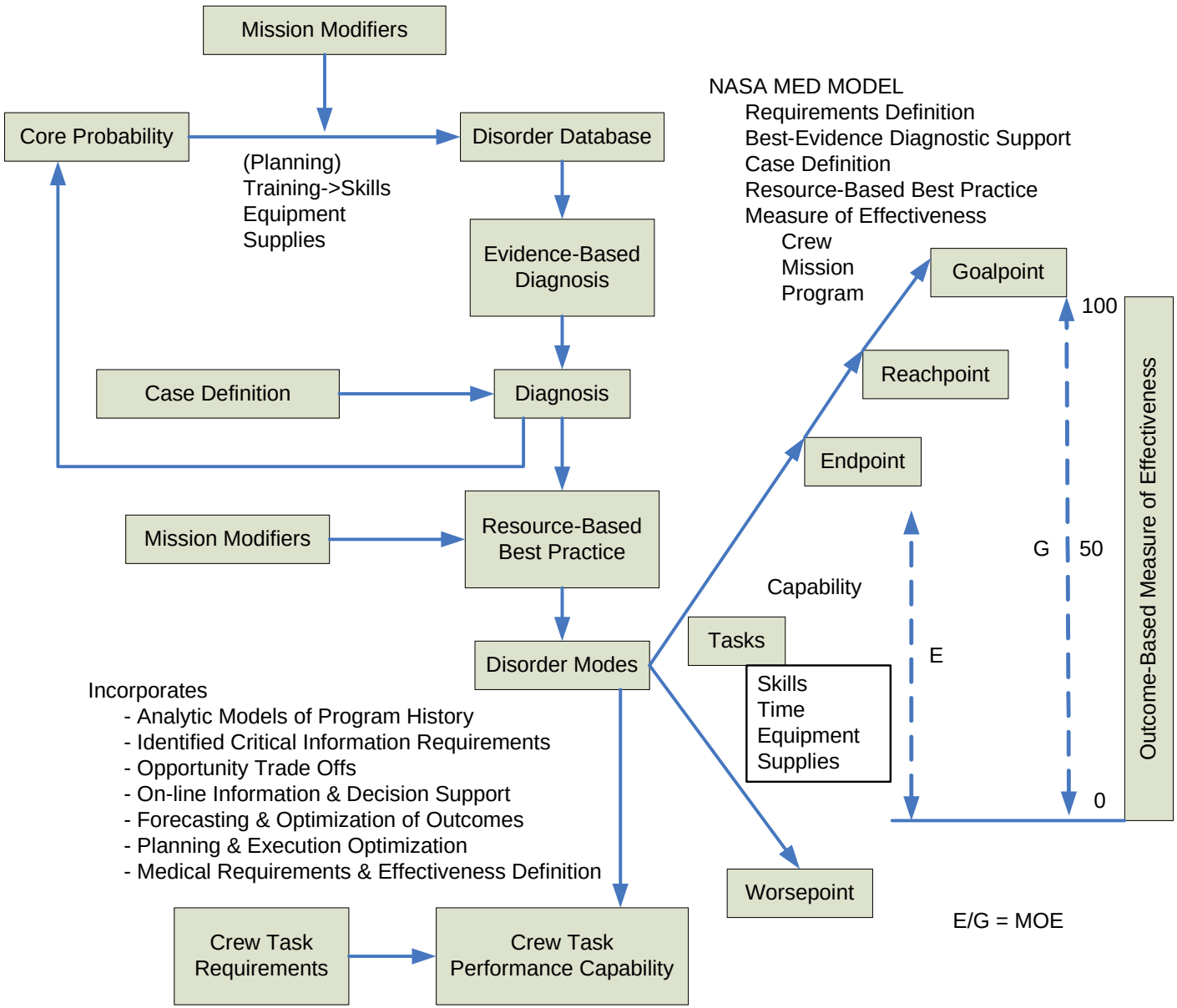
Objectives of Human System PRA Project

- Evaluate human health risks of space flight using Probabilistic Risk Assessment (PRA) techniques
- Update the human health aspects of PRA for International Space Station (ISS)
- Use ISS PRA heritage to develop methods to integrate human health risks into PRA for Exploration-class missions
- Overall: to enable an informed decision-making process

What is the Integrated Medical Model?

- Combation of astronaut and analog data to develop a more precise understanding of risk
- Determine risk in context:
  - Medical risk factors
  - Tasks being performed
  - Equipment availability
  - Caregiver skill set
  - Etc.

Integrated Medical Model



Integrated Medical Model (IMM) Blueprint

CREW ATTRIBUTES
- Crew ID #
- Age (years)
- Gender (M/F)
- Country of Origin/Life Expectancy (years)
- Medical History
  - Refer to EMR…
  - Blood Pressure
  - HDL/LDL
  - ECG
  - CBC
  - Etc,

TREATMENT PROTOCOL IN-FLIGHT
- Task ID#
- Medical Task Description
- Task Time Required (min.)
- In-flight Space Factor (1.3)
- Space Task Time (1.3 x min.)
- Required Equipment (ID#)
- Required Training (hours)
- Actual Training (hours)
- Human Reliability Index
- References/Info Sources

MEDICAL SYSTEM ATTRIBUTES
- Component ID#
- Item Description
- Mass (kg)
- Stowed Volume (cm3)
- Vehicle Power (Watts)
- Battery Power (Watts)
- Total Cost (U$)
  - Purchase Cost (U$)
  - Flight Cert. Cost U$)
  - Launch Cost (U$)
  - Sustain. Cost (U$)
- Reliability (% mission time)
- References/Info Sources

TREATMENT v OUTCOME ARRAYS
- Medical Disorder ID#
  - Disorder Description
  - Incidence Rate (events-crew-day)
    - Literature Review
    - Linear Regression Algorithm
  - Treatment Options
    - Terrestrial Standard of Care; Gold Standard
    - In-flight Treatment Option
    - Untreated Case
  - Outcome (% Whole Body Impairment)
    - Event Tree Diagram
      - Terrestrial Standard of Care
      - In-flight Treatment Option
      - Untreated
  - References/Info Sources

MISSION PROFILE
- Duration (Days)
- Crew Compliment (# of Crew)
- Vehicle System Resources
- Vehicle System Reliability Rates
- Operational Constraints
- Acceleration (g) Profiles
- References/Info Sources

MISSION TASKS
- Mission Task ID#
- Task Description
- Duration (minutes)
- % Mission Duration (%)
- Required Crew Capabilities
  - Physical
  - Cognitive
- Impeding Medical Disorder(s)
  - SNOMED #
- Reference/Info Sources

Integrated Medical Risk Modeling Strategy

- Identification of medical conditions which may occur
- A best estimate of the probability and frequency of each identified condition with mission modifiers
- A generalized, universal metric for quantifying the relative loss contribution of outcomes, i.e., the impact or severity and identification of probability of modes outcomes of a medical condition
- Identification of the medical resources (skills, equipment and supplies) necessary to provide optimized modes of outcome for conditions, i.e., the mitigations
- Use of a planning metric to rank effectiveness of nominated medical capabilities and their footprints for potentially achieving optimal outcomes **(minimizing health and performance risks)** compared to the Earth's unconstrained medical resource (a measure of relative effectiveness and a quantified measure of loss of health and performance)

Longitudinal Study of Astronaut Health (LSAH)

- Cohort study – 3 comparison subjects for each astronaut matched by age, sex and body mass index at baseline
- Purpose:
  - Examine mortality and morbidity rates (astronauts versus comparison subjects),
  - Determine the rate of illnesses and accidents that require medical care
  - Facilitate investigations of occupational
- Currently, there are 321 US astronauts and 982 comparison participants in LSAH.
- Surveillance of comparison group is being expanded to parallel the astronaut examination schedule.
- Recruitment of payload specialists with spaceflight experience has been initiated to increase cohort exposed to spaceflight.
- Contains MRID data plus ground-based clinical data

LSAH Purpose

- The Longitudinal Study of Astronaut Health has been primarily used to determine the effects of spaceflight on astronauts.
- Question: Can LSAH be used to inform the flight qualification decision making process? (i.e. when is a waiver warranted?)

Capabilities

- Determine the fit of a qualified-to-fly population against the current screening criteria.
  - Is the population near either extreme of the accepted range of values?
- Determine the number of medical incidents (ground and in flight)
- Determine the difference to an analog population
  - Potentially interpret analog data based on known differences in astronaut risk factors.

Issues

- The number of astronauts is small.
  - Cannot calculate an accurate incidence rate
- Astronauts are healthier than the general population
  - Makes it difficult to find a good analog

Summary

Summary

- Human systems PRA
  - Provides quantitative measures of probability, consequence, and uncertainty
  - Communicates risk and informs decision-making
- Human health risks rated highest in ISS PRA
  - Based on 1997 assessment of clinical events in analog operational settings
- Much work remains to analyze remaining human health risks identified in *Bioastronautics Roadmap*